

Appreciation of the Need for Informatics Support in Applied Clinical Research

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Introduction

The potential advantages of the use of informatics support for applied clinical research and clinical trials seems to be evident, however their real use is very variable. In medical informatics we tend to focus on tools for patient care rather than clinical research and it would seem profitable to address the question what are the barriers to current implementation of informatics tools to serve clinical research and what are the attitudes to informatics support expressed by personnel involved in clinical research. The quality of a clinical research project can be considered to relate to three major components, conception and protocol definition, organization and execution, and analysis and publication. Each component is vital to success and can benefit from informatics support. This study considers more the organization and execution component, where in fact much of the financial investment of the study is concentrated and which can be labour intensive and time consuming.

Methods

A questionnaire concerning attitudes to the use of informatics tools to assist research personnel employed to undertake clinical trials has been carried out with the research nurses registered with the Quebec Association of Research Nurses.

The aims of this study were to better understand how practically the uses of informatics tools could improve the quality of the practice of clinical trials, and to elucidate the factors which could inhibit or favour the introduction of informatics tools into the clinical research milieu.

The first two sections of the questionnaire concerned the research experience of the respondent, the 5 following sections considered the different stages of a clinical trial namely recruitment, the patient visit, communication of patient results to the coordinating centre, the management of patient follow-up, and management reports. The final 2 sections considered the different factors that might influence implantation

of informatics tools and the potential effect of informatics tools on different aspects of study quality.

Results

Of 170 questionnaires sent out, 57 were returned giving a response rate of 37%. The respondents had a mean of 6 years research experience and had participated in a total of 659 studies of which 74 (11%) had used some form of informatics support

Recruitment

25 respondents had already used an informatics tool to support patient recruitment. About half (52%) considered that the informatics support had reduced the time normally spent on recruitment however 16% saw no change and 12% thought the time spent had increased and 20% abstained.

Patient visits and patient follow-up

No participant had had the experience of using data collection tools in the presence of the patient. 52 studies out of 659 (8%) had been recorded first on paper and then entered into the computer. The recording of data in computer taken from the paper record results in a reduction of risk of both error and omission, easy and rapid production of reports, and the possibility of electronic data transmission. This is however at the expense of the extra work needed for recording the data twice, first on paper and then in computer. Computer tools to remind about and plan for future visits have been used in 9% of the studies undertaken, and only 4% used the electronic patient record as a follow up management prompting tool. The noted advantages were: rapid access to patient information, record more legible, and reduced stress as it reduced the fear of forgetting a patient visit.

Conclusions

We confirm the serious interest of the research nurse to use computing, as well as the need for a strengthened informatics implementation and support strategy by the local organisations responsible for clinical research.